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## **EXHIBIT 4-c**

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So, I would rather, if the Court is amenable, just deal with the four deposition notices. And if we can justify discovery later on in the case, we take it up at that time, whether it is an interrogatory or a request for admission or whatever.

THE COURT: Well, I appreciate your points, and I am not overly worried about the four deposition notices, you know, with respect their technical validity under the rules.

I mean, as I hope you-all can appreciate, this motion mushroomed at about 3 o'clock Wednesday afternoon into what I see before me today.

And I am devoting the time that I am devoting to it today because I think it is appropriate to begin, if not complete, the process of getting the whole thing under control.

MR. DESMARAIS: Thank you, Your Honor. And with respect to the schedule, Ms. Wetzler and I actually continued our meeting and conferring throughout the day yesterday. And at least between GSK and the Patent Office, we did agree on what dates would work for the briefing and what dates would work for the arguments.

So, I don't know that Your Honor needs to resolve that at this hearing. We can--

THE COURT: Well, I hope I don't have to impose a briefing schedule on you. While you have the floor, Mr.

Desmarais, give me some idea what range of dates you-all were 1 2 talking about. 3 MR. DESMARAIS: What-- And again, this is not, this is just between GSK and the Patent Office, we discussed last 4 night--5 6 THE COURT: I understand, you are not speaking for 7 anybody but your clients, I appreciate that. What--MR. DESMARAIS: Yeah. December 20 for the opening 8 9 summary judgment briefs and they would be crossmotions. The 10 responses were in January. The replies were early February. Argument date--11 12 THE COURT: Whatever Judge Cacheris sets. 13 MR. DESMARAIS: Exactly. But there was one, the one trick that we were having difficulty negotiating was I already 14 15 have a couple trials in February and March. So, Ms. Wetzler was kind enough to yield and we suggest a date to Judge 16 Cacheris in February on the condition that my trial that's 17 18 currently scheduled settles. If it doesn't settle, then we 19 are going to take the or propose the next available Friday 20 after the trial. 21 THE COURT: All right. MR. DESMARAIS: So, that's how we sort of worked out 22 23 the meet and confer last night. 24 THE COURT: All right. Thank you. 25 Ms. Wetzler, what I am inclined to do, I am going to

36 1 hear any response that you want to make now, but I will tell 2 you now, what I am beginning to think about doing is taking 3 this motion under advisement until two weeks from today, 4 asking for some supplemental authority if not supplemental 5 briefing, and giving you, giving you collectively an 6 opportunity to continue the discussions that everybody has now 7 alluded to. 8 Would you have any problem with that course of 9 action? 10 MS. WETZLER: Yes and no, Your Honor. 11 THE COURT: All right. 12 MS. WETZLER: The reason why we do have some pause 13 is it goes to why we started our brief with the way this case 14 was set up before the preliminary injunction was issued. And 15 what that was was at the preliminary injunction hearing Mr. 16 Desmarais said this case could go forward, could be resolved 17 in one-and-a-half months. And Tafas had already agreed to a briefing schedule that would have had their first brief due 18 19 October 29. We then changed that to November 7. 20 So, what we are concerned about is that the 21 plaintiffs were previously ready to get this done very expeditiously and now that the preliminary injunction has 22 23 issued, they are looking to, for a longer schedule. 24 We see no reason why this case should not be able to 25 go forward with the expediency that the parties, the

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plaintiffs were originally willing to undertake. So, my concern or my hesitation is that further two weeks means that a briefing schedule couldn't even start until much later than that, which pushes this case well beyond where the parties were originally able and willing to have this case decided. THE COURT: All right. MS. WETZLER: I would though like to address some of the points that were made here, if I may, Your Honor. THE COURT: All right. MS. WETZLER: First, on the question of whether the record is complete. I think as Your Honor was hinting at in some of the questions you were asking Mr. Nealon, many of the, the vast majority of the questions in this case are pure questions of law for which there is no need for a record, much less discovery. The question of whether something is substantive or

The question of whether something is substantive or procedural, as Your Honor alluded to, I am not sure where Mr. Nealon is getting this notion of it turns on economic impact. But to the extent that were true, and I don't know what the authority is for that, that certainly is, the economic impact is well established in the record, it is throughout it.

The question of whether the PTO has the power to issue these rules is also a question of law, it has to do with what power Congress has delegated as far as rule making

authority to the PTO and whether the PTO has acted consistently with the Patent Act. Those are pure legal questions.

And also the third question, the constitutional question of compliance with the Patent Act. The PTO's position is that that claim cannot go forward for a number of threshold reasons. But even if it did, the question there is simply whether the PTO acted in an irrational manner. That is much like arbitrary and capricious review, something that could be decided and should be decided on the vast record that is already before the Court.

So, that's first, Your Honor, the issue. Most of this is about issues of law. So, let's talk about what, when the Court, when the parties would need a record. And that's primarily the question of whether there is arbitrary and capricious, when the Court undertakes arbitrary and capricious review.

The first issue about this belief about the way it was put in the brief was that there was private back room decision making. I think the way that Mr. Nealon discussed it here was, I think he actually used the same phrase, and also said an inner circle of rule making.

Your Honor, there is a D.C. Circuit case that's directly on point here, which is the <u>In re subpoena duces</u>

tecum, it is a very long title, but the cite is 156 F.3d 1279.

39 And it is quoted at length in a decision by Judge Facciola 1 very recently called Blue Ocean Institute versus Gutierrez. 2 And I would like to give that case to the Court, if I may, as 3 well. 4 5 THE COURT: All right. 6 MS. WETZLER: I have highlighted the relevant 7 section, but the significant point, there are numerous significant points in this decision. The first is in quoting 8 9 the D.C. Circuit, the Court explains, "when a party challenges 10 agency action as arbitrary and capricious, the reasonableness of the agency's action is judged in accordance with its stated 11 12 reasons. Agency deliberations not part of the record are deemed immaterial. That is because the actual subjective 13 motivation of agency decision makers is immaterial as a matter 14 of law unless there is a showing of bad faith or improper 15 16 behavior." 17 And I will come back in a moment to the question of bad faith. But what the Court looks at is the stated reasons, 18 the subjective intent. All of this is absolutely irrelevant 19 20 unless there is a showing of bad faith. That's quoted from 21 the D.C. Circuit. The other significant aspect of the Blue Ocean 22 23 Institute case is what it says about privilege logs. And in 24 this case, this is a case much like this one where the

plaintiffs came in and they said, we believe the record is

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40 1 incomplete, we think there are things that are missing. 2 And what the, what Judge Facciola said in response 3 to that is, "under the most traditional understanding of how a 4 party meets its burden of proof, Blue Ocean, the plaintiff, is 5 reduced to theorizing that the documents may exist, which fails to overcome the presumption that the record is 6 7 complete." 8 And so, in addition, what Judge Facciola had is they didn't need to provide a privilege log because, quite simply, 9 10 deliberative materials don't belong in a record. They are 11 irrelevant as the D.C. Circuit has said. 12 And so, consequently if we look at note 4 of Judge 13 Facciola's decision, what he said was, "it is unfair to 14 criticize NMFS, which is the government in this case, for not 15 claiming a privilege and filing a privilege log as to documents it claims should not be in the administrative record 16 in the first place." 17 18 And that's the case here, Your Honor. These 19 deliberative, they are of course deliberative materials. deliberative materials don't belong in a record, they are 20 immaterial. And, therefore, we have no obligation to provide 21 22 a privilege log. 23 We asked--24 THE COURT: Well, Mr. Nealon's point, I expect, is

that he needs a privilege log to determine whether the 25

41 materials that you claim were deliberative were in fact 1 deliberative. 3 MS. WETZLER: Your Honor, there is a presumption of 4 regularity of what the government does. 5 THE COURT: I understand. MS. WETZLER: And unless Mr. Nealon could provide 6 7 specific reasons to believe that what we have designated as 8 privileged is not privileged, the reasoning of Judge Facciola is incredibly compelling. What he says is, "creating such a 9 10 new"--11 THE COURT: I will tell him you said that. MS. WETZLER: Please do. "Creating such a new 12 13 burden on the agency, the parties and the Court by forcing production of even a limited number of interagency 14 deliberative documents, requires a clear command from the 15 16 Court of Appeals, particularly in light of the unequivocal statement by that Court that such materials are not part of 17 the administrative record when an agency decision is 18 19 challenged as arbitrary and capricious." 20 This is a burden that the Government should not have to bear because in any administrative decision there are going 21 22 to be deliberative materials, there are going to be extensive 23 deliberative materials--24 THE COURT: I understand, you are arguing the rule, he is arguing the exception. I appreciate that. 25

7 MS. WETZLER: Okay. Then moving on to another point 2 as to why Mr. Nealon believes the record is incomplete. He 3 focuses on preproposed rules materials and why those aren't in the record. 5 Quite simply, Your Honor, what the Court is 6 reviewing is not the proposed rules. The Court reviews the 7 final rules. And what we have done is provided an administrative record that is complete as to how those final 8 9 rules were decided. That's all that is before the Court. 10 It doesn't matter how they created the proposed rules or what went on there. What the Court is reviewing is 11 12 the final rules. And that's what we have proposed, that's 13 what is in the administrative record, appropriately so. 14 And further, Your Honor, the GSK brief raises six 15 issues that they believe are incomplete. And Tafas has 16 adopted those by, incorporated those into his brief by 17 reference. And I would, I would like the opportunity to very 18 briefly explain why each of those is not incomplete in the record. 19 20 The first is a claim that there were--21 THE COURT: What I would like to get from you, Ms. 22 Wetzler-- I am going to take this under advisement. MS. WETZLER: Yes, Your Honor. 23 THE COURT: And I would like for you to respond to 24 25 that in writing.

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               MS. WETZLER: I would be happy to do that.
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               THE COURT: Okay.
               MS. WETZLER: Then moving on to the question of bad
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     faith.
               THE COURT: I don't need to hear you further on that
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     today.
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               MS. WETZLER: I am sorry?
               THE COURT: I don't need to hear you further on that
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     today.
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               MS. WETZLER: Yes, Your Honor, I will put that in
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     writing as well.
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               Further on the issue of FOIA which Mr. Desmarais has
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     raised, I just want to be perfectly clear that FOIA and
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     District Court discovery are entirely independent processes.
               THE COURT: All right.
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               MS. WETZLER: So, this case cannot be held up for
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     FOIA litigation. FOIA litigation goes or any FOIA requests--
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               THE COURT: You don't need to convince me of that.
               MS. WETZLER: So, that's all then that needs to be
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     said about that.
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               As far as the briefing schedule. What Mr. Desmarais
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     said is in fact what GSK counsel and I were able to talk about
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     yesterday, but that was a schedule, I want to be clear, if the
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     Court finds no discovery to be appropriate. And I would like
     to provide the Court the proposed order that we at least
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      agreed to so that the Court understands the parameters. This
      is language that was negotiated yesterday.
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               THE COURT: I will be happy to look at that, but I
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     was interested primarily in, you know, a general notion of
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     what end dates you-all had in mind, and I appreciate the need
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     to work back from that.
               All right.
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               MS. WETZLER: So, Your Honor, just to conclude then.
     The order we just gave you has to do with if there is no
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     discovery. We do believe that there should be no discovery in
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     this case. There is a 127 page explanation.
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               THE COURT: I understand.
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               MS. WETZLER: And a 10,000 page record.
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               THE COURT: A 10,000 page record.
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               MS. WETZLER: Yes, Your Honor, you have got it.
     that's-- What we also need in this case is clear expeditious
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     resolution. It is important to the PTO to allow their rule
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     making to come to a final resolution, to go into effect. And
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     we need clear guidance from the Court and not continued
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     possibilities of discovery down the road.
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               THE COURT: I appreciate that.
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               MS. WETZLER: Thank you, Your Honor.
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               MR. NEALON: Your Honor, could I just be heard real
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     quick on the scheduling?
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               THE COURT: I don't need to hear you, Mr. Nealon.
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